REMARKS

By this Amendment, Applicants propose to amend independent claims 200 and 212. Applicants also propose to add new claims 237-323. No new matter has been added.

On page 2 of the Final Office Action, claims 228, 229, 235, and 236 were objected to under 37 CFR § 1.75(c) as being of improper dependent form for allegedly failing to further limit the subject matter of a previous claim. The Office Action states that the "Examiner does not see how Applicant[s] can recite the use of active suction in the independent claim and then recite the "not use" of active suction in the dependent claims." Claims 228, 229, 235, and 236 also were rejected under 35 U.S.C. § 112, first paragraph, "because the specification, while being enabling for use of active suction, does not reasonably provide enablement for use of active suction and non-use of active suction simultaneously." The Office Action further states that "[i]n the dependent claims, in the same step of the method [which uses active suction], Applicant claims not using active suction." Applicants respectfully disagree.

Independent claims 200 and 212 recite in pertinent part "subsequent to dilating the lesion, using active suction to induce retrograde flow within the blood vessel." Claim 228 depends from claim 200 and claim 235 depends from claim 212, and each of these dependent claims further limits its respective independent claim by reciting "wherein advancing the dilation balloon across the lesion to be treated includes advancing the dilation balloon without active suction." Thus, independent claims 200 and 212 do not require suction until after the lesion has been dilated, and dependent claims 228 and 235 indicate that a step prior to dilating the lesion, e.g., advancing the dilation balloon, does

not use active suction. Support for this can be found, for example, in paragraph 93 of the specification.

Claim 229 depends from claim 200 and claim 236 depends from claim 212, and each of these dependent claims further limits its respective independent claim by reciting "advancing a guidewire across the lesion to be treated without active suction." Thus, independent claims 200 and 212 do not require suction until after the lesion has been dilated, and dependent claims 229 and 236 indicate that a step prior to dilating the lesion, e.g., advancing a guidewire across the lesion, does not use active suction. Support for this can be found, for example, in paragraph 90 of the specification. For these reasons, reconsideration is requested.

On pages 3-4 of the outstanding Final Office Action, claims 200-204, 207-216, 219-227, and 230-234 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierpont, U.S. Patent No. 5,484,412, in view of Parodi, U.S. Patent No. 6,206,868. The Examiner repeated the rejection from the previous office action. In addition, the Examiner stated that "[i]n Pierpont, when the at least one sealing surface is deployed within the blood vessel, it creates a tight seal against the blood vessel. At this location, the at least one sealing surface does indeed occlude normal antegrade flow. ...[A]t the location where the deployed at least one sealing surface meets the wall of the blood vessel, any blood flow is occluded."

Applicants do not necessarily agree with the Examiner's characterizations of Pierpoint, for example, that there is occlusion of antegrade flow at a pinpoint spot where a balloon contacts the blood vessel. However, in an effort to further prosecution of this application, Applicants have amended independent claims 200 and 212 to be more

specific as to where antegrade flow is occluded, as suggested by the Examiner. Each of claims 200 and 212 now recite in part "prior to advancing the dilation balloon across the lesion to be treated, deploying the at least one sealing surface to occlude normal antegrade flow within the blood vessel adjacent to the lesion to be treated." Applicants respectfully submit that even if Pierpont does occlude flow at the point where its balloon contacts the blood vessel wall, it does not teach or suggest occluding normal antegrade flow adjacent to the lesion to be treated.

In addition, Pierpont cannot be modified as suggested by the Examiner to occlude normal antegrade flow adjacent to the lesion to be treated. The structure of Pierpont includes a plurality of perfusion ports 40 that allow blood to flow through the anchoring catheter 22 and down the coronary artery while the balloons are inflated. These perfusion ports 40 render Pierpont incapable of occluding normal antegrade flow adjacent to the lesion to be treated. Therefore, the combination of Pierpont and Parodi as suggested in the Office Action would not result in the invention as claimed. Normal antegrade flow must be stopped prior to inducing retrograde flow. Thus, to successfully use the retrograde flow taught by Parodi with the device of Pierpont, it would first be necessary to eliminate the perfusion ports of Pierpont. However, Pierpont teaches that the perfusion ports are a critical structural element necessary to prevent stoppage of oxygenated blood flow. Pierpont states that "[t]his is very critical so as to continue to support the heart muscle 10 with oxygen while the balloons are inflated and anchoring the guiding catheter to the coronary artery." Col. 4, lines 44-49. Removing the perfusion ports of Pierpont would render the Pierpont invention unsatisfactory for its intended purpose and change the principle of operation of Pierpont. There is no suggestion or

motivation to make a proposed modification that would render a prior art invention unsatisfactory for its intended purpose. *In re Gordon*, 733 F.3d 900 (Fed. Cir. 1984). In addition, if a proposed combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references do not support a *prima facie* case of obviousness. *In re Ratti*, 270 F.2d 810 (CCPA 1959).

For at least these reasons, independent claims 200 and 212 are patentable over Pierpont and Parodi, either alone or in combination. Dependent claims 201-211 and 213-236 are also patentable over Pierpont and Parodi for at least the same reasons as independent claims 200 and 212. Withdrawal of this rejection and reconsideration of the claims is requested.

By this Amendment, Applicants propose to add new claims 237-323. Each of new independent claims 237 and 252 recites in part "prior to advancing the dilation balloon across the lesion to be treated, deploying the at least one sealing surface to occlude normal antegrade flow within the blood vessel distal to the lesion to be treated." Each of new independent claims 266 and 281 recites in part "prior to advancing the dilation balloon across the lesion to be treated, deploying the at least one sealing surface to occlude normal antegrade flow within the blood vessel distal to the at least one sealing surface." Each of new independent claims 295 and 310 recites in part "prior to advancing the dilation balloon across the lesion to be treated, deploying the at least one sealing surface to occlude normal antegrade flow within the blood vessel across a cross-section of the blood vessel." As discussed above with respect to independent claims 200 and 212, Pierpont does not teach occluding normal antegrade flow distal to the at least

one sealing surface, distal to the lesion to be treated, or across a cross-section of the blood vessel. For at least these reasons, new claims 237-323 are patentable over each of Pierpont and Parodi, either alone or in combination.

Claims 205, 206, 217, and 218 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Pierpont in view of Parodi, and further in view of Barbut, U.S. Patent No. 6,146,370. The Office Action relies on Barbut for teaching advancing a stent into a blood vessel. However, Barbut does not cure the deficiencies of Pierpont as discussed above. Claims 205 and 206 depend from independent claim 200, and claims 217 and 218 depend from independent claim 212, and therefore, for at least the same reasons discussed above with regard to independent claims 200 and 212, claims 205, 206, 217, and 218 are patentable over each of Pierpont, Parodi, and Barbut, either alone or in any combination. Withdrawal of this rejection and reconsideration of the claims is requested.

Claims 201-211 and 223-229 depend from independent claim 200, and are therefore allowable for at least the same reasons claim 200 is allowable. Claims 213-222 and 230-236 depend from independent claim 212, and are therefore allowable for at least the same reasons claim 212 is allowable. Claims 238-251 depend from independent claim 237, and are therefore allowable for at least the same reasons claim 237 is allowable. Claims 253-265 depend from independent claim 252, and are therefore allowable for at least the same reasons claim 252 is allowable. Claims 267-280 depend from independent claim 266, and are therefore allowable for at least the same reasons claim 266 is allowable. Claims 282-294 depend from independent claim 281, and are therefore allowable for at least the same reasons claim 281 is allowable. Claims 296-309 depend from independent claim 295, and are therefore allowable for at least the same

reasons claim 295 is allowable. Claims 311-323 depend from independent claim 310, and are therefore allowable for at least the same reasons claim 310 is allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore at least some of the dependent claims also are separately patentable.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 200-323 in condition for allowance. Applicants submit that the proposed amendments of claims 200 and 212 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Applicants further submit that the proposed addition of new independent claims 237, 252, 266, 281, 295, and 310 and dependent claims 238-252, 253-265, 267-280, 282-294, 296-309, and 311-323 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented some new arguments as to the application of the art against Applicants' invention. It is respectfully submitted that the entering of the Amendment would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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